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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/328,296	06/08/99	SIEGALL	C 9632-005

HM12/0502

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EXAMINER	
NIKODEM, D	
ART UNIT	**PAPER NUMBER**
1633	6

DATE MAILED: 05/02/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/328,296	SIEGALL ET AL.	
	Examiner	Art Unit	
	David Nikodem	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ___ 30 days FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☐ Responsive to communication(s) filed on ____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) ____ is/are pending in the application.

4a) Of the above claim(s) ____ is/are withdrawn from consideration.

5)☐ Claim(s) ____ is/are allowed.

6)☐ Claim(s) ____ is/are rejected.

7)☐ Claim(s) ____ is/are objected to.

8)☒ Claims 1-37 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on ____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on ____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) ____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

14) ☐ Notice of References Cited (PTO-892)
15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
16) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ .
17) ☐ Interview Summary (PTO-413) Paper No(s). ____ .
18) ☐ Notice of Informal Patent Application (PTO-152)
19) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9 and 34, drawn to antibodies, protein fragments of antibodies and fusion proteins of antibodies, classified in class 530, subclasses 387.1, 387.3, 387.7 and 387.9.

II. Claims 10-20, drawn to nucleic acids, host cells and methods to produce proteins, classified in class 536, subclasses 23.1, 23.53 and 24.33, and class 435, subclasses 69.1, 320.1, 325 and.

III. Claims 21-25 and 36, drawn to pharmaceutical compositions, classified in class 514, subclasses 2 and 4.

IV. Claims 26, 27, 32, 33 and 37, drawn to methods for the treatment or prevention of cancer, classified in class 435, subclasses 326, 328 and 330 and in class 514, subclass 2.

V. Claims 28, 29, 32 and 33, drawn to methods for activating or augmenting the immune response, classified in class 435, subclasses 326, 328 and 330 and in class 514, subclass 2.

VI. Claims 30 -33, drawn to methods for the treatment or prevention of an immune disorder, classified in class 435, subclasses 326, 328 and 330 and in class 514, subclass 2.

VII. Claim 35, drawn to transgenic animals, classified in class 800, subclasses 8, 10, 13 and 295.

Note: Claims 32 and 33 are generic among groups IV, V and VI. These claims encompass multiple inventions and thus the claims will be examined only to the extent that they read on the elected invention. Upon election to a group including these claims, the claims should be amended to reflect the elected invention.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions IV, V and VI are patentably distinct, each from the other. Invention IV is drawn to a method for the treatment or prevention of cancer, whereas Invention V is drawn to a method for activating or augmenting the immune response, whereas Invention VI is drawn to a method for the treatment or prevention of an immune disorder. The inventions are distinct and independent because each invention is drawn towards a wholly different type of method, each having different and unrelated method steps and/or with different end results or goals. Furthermore, different materials and reagents and the development of different protocols are needed to practice each invention as claimed. In view of the forgoing, the search between the three inventions would not be coextensive.

3. Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be isolated from serum of an animal immunized with CD40, or a fragment thereof.

4. Inventions I and each III, IV, V and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody, protein fragments of the antibody and fusion protein can be used to purify CD40.

5. Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids can be used as probes for *in situ* hybridization and/or PCR.

6. Inventions II and each IV, V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have

different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the nucleic acids of Invention II are not needed to practice either Invention IV, V or VI. Although the nucleic acid encodes the protein used in Inventions IV, V and VI, the nucleic acid can be used as a primer for PCR. Inventions IV, V and VI utilize a protein, or protein fragment thereof, which is wholly different in structure and function from the nucleic acids of Invention II.

7. Inventions VII and each I, III, IV, V, and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Inventions I, III, IV, V, and VI are not needed for the generation and/or use of Invention VII; each invention is distinct and independent. The transgenic animal of Invention VII can be used a model for disease and does require Inventions I, III, IV, V and/or VI to make and/or use the invention as claimed. Furthermore, the inventions have wholly different modes of operations and different materials and reagents and the development of different protocols are needed to make and/or use each invention as claimed. In view of the forgoing, the search between the three inventions would not be coextensive.

8. Inventions II and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product (MPEP § 806.05(h)). In the instant case although the nucleic acids of Invention II are needed to generate a transgenic animal, the nucleic acids can be used to generate probes for *in situ* hybridization and or/ PCR.

9. Inventions III and each IV, V and VI are patentably distinct, each from the other. Invention III is drawn to pharmaceutical compositions, whereas Inventions IV, V and VI are drawn to methods of treatment. Although the inventions utilize an antibody, protein fragment of the antibody and/or fusion protein, the inventions are distinct and independent because each invention is drawn towards a wholly different type of final product and/or end result or goal. The pharmaceutical composition contains other products/compounds, such as a pharmaceutically acceptable carrier. The methods of Inventions IV, V and VI are wholly different, each from the other, and utilize products differently to achieve vastly different end results or goals. Therefore, different materials and reagents and the development of different protocols are needed to practice each invention as claimed. In view of the forgoing, the search between the four inventions would not be coextensive.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Nikodem, Ph.D. whose telephone number is (703) 308-8361. The examiner can normally be reached on M-F, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3230 for regular communications and (703) 305-3230 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.

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April 27, 2000

JOHN L. LeGUYADER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600